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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,926	08/20/2003	James Rudolf Meyer	104336.01	4763
25944	7590	09/27/2006	EXAMINER	
OLIFF & BERRIDGE, PLC			GORDON, BRIAN R	
P.O. BOX 19928			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22320			1743	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,926

Applicant(s)

MEYER ET AL.

Examiner

Brian R. Gordon

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7-18-06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 18, 2006 have been fully considered but they are not persuasive. Applicant has amended the claims, but has not overcome the previous 112 rejections of the prior Office Actions. The amendments to the claim have incorporated new matter as explained below.

As to the art rejections, it should be noted the probe assembly of the prior art does not have to be disclosed as being used as a means for washing any particular device. It is only required that the prior art disclose a probe assembly with two probes (one angled) that is structurally capable of aspirating fluid and the other capable of dispensing a fluid.

Referring to the probe assembly as a washing module does not further limit the structure. One can refer to the assembly by any name desired. Electing to refer to the assembly as a washing module simply expresses the intended use of probe assembly. There is nothing precluding applicant or anyone else from employing the probe assembly to perform another function besides washing. For example, the dispensing probe can simply be used to dispense reaction fluids in a target location. Regardless of how one employs the device the structure remains constant. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

It should further be noted that the reasoning why for angling the device in the prior art is not required to be the same as that disclosed by applicant.

Applicant states Shaw does not necessitate a washing step. While such an argument is directed to intended use of the structure, it should be noted Shaw discloses, dispensing mechanisms can be used in any analyzer necessitating the dispensing of a reference liquid or some other standard liquid, such as a wash liquid (column 5, lines 24-27).

For reasons given herein the previous rejections are hereby maintained.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 1 by simply replacing the term "well holder" with "well". First it should be noted, applicant made the amendment without providing a location of where in the specification such an amendment is supported. After a cursory review of the specification the examiner fails to locate where an "assay device well" is mentioned. The only reference to well that examiner has found is that of the "storage wells" (1-3 and 43-45). Is it applicant's position that the "well" mentioned in the claims is the same as the "storage wells"? If so, then the claims should use consistent language

with that of the specification in order to avoid confusion. If not, then such an amendment is considered new matter.

As to claim 1 it is unclear if applicant intends to claim the "well" as an element of the invention. While the well is mentioned in the claim, it is not positively claimed as an element of the invention. Furthermore it is unclear actually which element applicant considers as the well. Is the well holder the tray 20, or tray support housing 110, or some other element. For consistency, the examiner suggests using the same terminology employed in the specification within the claims in order to clearly reflect which elements are being claimed. The claim as presently drafted describes a washing module and its intended interaction with a well that is not an element of the module.

It should be further noted that the preamble of the claim expresses that the intended use of the module is for washing an assay device, however the assay device is not positively claimed as an element of the invention, hence the only structural requirements of the claim is a wash delivery probe and an aspirator probe mounted to a movable support and the aspirator probe is mounted at an angle on the support. It should be noted that the probe assembly of the prior art does not have to be disclosed as being used as a means for washing any particular device. It is only required that the prior art disclose a probe assembly with two probes (one angled) that is structurally capable of aspirating fluid and the other capable of dispensing a fluid.

As to the "whereby" clause:

It has been held that the functional "whereby" statement does not define any structure and accordingly can not serve to distinguish. *In re Mason*, 114 USPQ 127, 44 CCPA 937 (1957).

Claim 1 recites the limitation "mounted an angle to vertical" in line 4. This phrase is unclear. It appears as if a more appropriate description would be, "mounted an angle to a vertical axis".

Claim 2 recites the limitation "the wash location of the well " in line 2. There is insufficient antecedent basis for this limitation in the claim. As stated above the "well" is not claimed as an element of the invention. Furthermore, it is unclear what is the structural relationship of "a probe wash reservoir" and the claimed elements of the module. Attempting to claim the location of reservoir in reference to the unclaimed well is improper. The reservoir is not defined by any structure, but yet it is defined in relevance to where the probe may be placed. Therefore, a probe having the ability to be positioned at a lower level than a desired level would be considered as being structurally equivalent. What element makes up the wash reservoir and how is it structurally connected to the other elements? How is the reservoir related to claimed elements (the well is not positively claimed as an element of the invention)? It should further be noted that applicant's specification [0103] states, "A probe wash reservoir 113 is located below the location of a carrier tray." If such a phrase is employed in the claims, the carrier tray must be positively claimed as an element of the invention.

Claim 2 appears to be directed to a process limitation or intended use. The claim narrates what is intended to happen in a certain situation or under specified circumstances (in the absence of a well). The claim expresses an intended use or movement of the support under certain conditions. This is not considered a structural limitation, but is directed to intended use or a specified process.

Furthermore, it is unclear what applicant considers as the vacuum source, for the vessel is connected to multiple elements in the vacuum system. However the examiner assumes the vacuum source is vacuum pump 129. Applicant did not state in the response if the examiner's assumption is correct or in error. As such, the examiner hereby assumes the assumption is correct.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As stated below there is no support for an assay device well as claimed. Claim to includes new matter for the specification does not describe the reservoir as having any relation to a "well" as claimed. There is no "well support" mentioned in the specification as claimed in claim 5. There is an incubation/shaker module 17 disclosed for shaking carrier tray holding storage wells [0076].

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. US 5,085,832 in view of Harris et al. US 5,650,122.

Shaw et al. disclose a liquid dispensing mechanism is described for moving a dispensing tip from an aspirating station to a dispensing station, preferably through a circle of rotation (abstract).

As seen in figure 1 the device is mounted at an angle and is capable of moving at an angle.

The reference discloses single probe is capable of dispensing and aspirating. However, Shaw et al. fails to disclose the employment of a second probe.

Harris et al. disclose reaction wells are washed with high-pressure jets of wash solution and are aspirated so as to advantageously utilize fluid meniscus on top of fluid contained in the wells. The apparatus can be adjusted to perform a variety of different ELISA-type tests (abstract).

As best seen in FIG. 14, each processing station has an aspiration manifold 466 having eight vertical aspiration tubes. Each aspiration tube has an outlet 470, approximately at the center of the manifold, to reduce pressure differences between tubes due to laminar flow. Each aspiration tube also has a fluid inlet 472 positioned to be above the level of the top 474 of the reaction wells when the processing stations are in the raised position. The length of vertical travel of the processing stations is sufficient to place the fluid inlet 472 adjacent to the transparent well bottom 476 when the processing stations are in the lowered position.

A partial vacuum is formed in the aspiration manifold 466 by aspiration lines 58, 74. A partial vacuum is established, as previously discussed, by vacuum pump 62. The vacuum pump 62 produces a relatively weak vacuum. The aspiration lines 58, 74 can be independently controlled by the computer control system 14 through conventional solenoid-operated valves 477, 478, respectively.

After the patient sample and unbound analyte (or diluted patient and unbound analyte) have been removed by the aspiration tubes, wash tubes 484 vigorously wash the aspiration tubes and the reaction wells with high-pressure jets of wash solution from wash line 66 for the first processing station and from second wash line 78 for the second processing station.

Each processing station has a wash manifold 486 which is charged with a high-pressure stream of wash solution by the solenoid-operated liquid pump 68 or second solenoid-operated liquid pump 76.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Shaw et al. to incorporate the washing probe as taught by Harris et al in order to allow for the vigorous cleaning of the elements at stations A and B.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw in view of Harris as applied to claims 1-4 above, and further in view of Schramm, US 4,925,629.

Shaw in view of Harris do not disclose a means for shaking.

Schramm discloses diagnostic device (10) includes a plurality of standard solutions for being dispensed into a row of wells (20). The invention further provides a mixing mechanism for agitating the entirety of a microtiter plate seated thereover (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention modify the modified teachings of Shaw to incorporate an agitating means as taught by Schramm to enhance the mixing of the reagents within the wells.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to be 'B. R. M.' or similar, written in a cursive style.

brg